

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 32026P WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/013782	International filing date (<i>day/month/year</i>) 03.12.2004	Priority date (<i>day/month/year</i>) 04.12.2003
International Patent Classification (IPC) or national classification and IPC G01 N33/487, B01 L3/00		
Applicant ROCHE DIAGNOSTICS GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-11 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-21 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/3-3/3 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-21</u>	YES
		Claims <u></u>	NO
	Inventive step (IS)	Claims <u></u>	YES
		Claims <u>1-21</u>	NO
	Industrial applicability (IA)	Claims <u>1-21</u>	YES
		Claims <u></u>	NO
2.	Citations and explanations (Rule 70.7)		
	Reference is made to the following documents:		
	D1: US-B1-6 284 550		
	D2: WO 02/49763		
	D3: WO 97/46887 A.		
	Novelty:		
	<p>Document D1 is the closest prior art. It discloses an analytical test element according to the preamble of claim 1 (see figure 1 and the corresponding part of the description). However, the test element according to claim 1 differs from that according to document D1 in that it has a hydrophobically structured surface in at least one area around the feeding zone (PCT Article 33(2)).</p> <p>This distinguishing feature is also found in dependent claims 2-20 and, in a corresponding manner, in the independent method claim 21.</p>		

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Inventive step:

1. The technical effect of the above distinguishing feature is that of preventing the adhesion of sample material in the area of the feeder zone and hence of avoiding contamination of the measurement device when the test element is used.

Document D1 already suggests a solution to this problem, that is to say, the provision of small dams or barriers (see column 2, lines 52-57). Document D1 expressly states that these features are designed to prevent overflow and contamination (column 4, bottom, to column 5, top). Consequently, the technical effect to be achieved with the solutions disclosed in document D1 and claim 1 is the same.

The objective technical problem to be solved is therefore that of providing a **different, alternative** test element according to document D1, wherein the sample material likewise does not adhere in the area of the feeding zone.

(The problem of interest as stated in the application, that is to say, the provision of an embodiment wherein the adhesion of sample material is largely prevented in the entire surface area around the sample feeding zone, does not correspond to the above distinguishing feature, that is to say, the feature of the solution, firstly because the application does not mention

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	<p>"the entire surface area around the sample feeding zone" but merely "at least in an area around the feeding zone", that is to say a partial area, and secondly because means for avoiding adhesion and contamination are already known from document D1.)</p> <p>2. What is decisive for the evaluation with regard to inventive step of the stated problem and the solution thereto, is whether a different, alternative solution with which the same effect can be achieved is known from the prior art.</p> <p>Document D2 describes a device for receiving and dispensing liquids with capillary needles, wherein the device has a surface with a hydrophobically structured microstructure in the area of the capillary opening(s) (page 7, penultimate paragraph). According to document D2, this surface modification serves to facilitate cleaning, which, to a person skilled in the art, must be considered equivalent to poor adhesion of the "sample material". However, therein document D2 discloses a solution to the above problem which is exactly that disclosed in the present claim 1.</p> <p>The fact that this surface treatment takes place "inside" the device according to document D2 can be disregarded for the purpose of the evaluation with regard to inventive step, since claim 1 is not restricted to an arrangement of the feeding zone on the "outside". Moreover, document D1 need not contain a reference to the use of a</p>

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	<p>hydrophobically structured surface, since novelty is considered established.</p> <p>Since nothing would appear to prevent a person skilled in the art from taking into consideration the solution disclosed in document D2, he would consider a hydrophobically structured surface in the area of the feeding zone a known alternative for the solution of the objective, technical problem of interest, and would therefore arrive at the subject matter of claim 1 without thereby having to exercise inventive skill (PCT Article 33(3)).</p> <p>Similar considerations apply to independent claim 21.</p> <p>3. The features of the dependent claims would appear to be embodiments of the test element which are known from document D1 and D2 (claims 2-7, 14, 15) or which are routine practice in the art (claims 8-10, 11-13, 16-20; see, for example, document D3) .</p> <p>Industrial applicability:</p> <p>Industrial applicability is established (PCT Article 33(4)) .</p>

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1. Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not cite document D2 or indicate the relevant prior art disclosed therein.
2. The features of the claims are not followed by reference signs placed between parentheses (PCT Rule 6.2(b)).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Dependent claim 11 is unclear (as, therefore, are claims 12-15) since it is not clear how the **test element** is restricted, owing to the fact that it is **designed** to be housed inside **a cartridge**.